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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,761	12/14/2001	Izumi Arai	P67386US0	3663

136 7590 06/18/2004

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	5

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,761	ARAI, IZUMI	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12/14/2001

is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-5 are pending and subject to current examination.

The format of the claims on pages 1-4 "method for the neogenesis of cell age claims" is improper. A claim is to be composed of one sentence (MPEP 608.01(m)). These claims have not been examined.

The drawings are objected to because the numbering is confusing. Exactly what is being numbered?

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/926,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the are obvious variations using the method steps of producing replacement organs by cloning techniques involving parthenogenesis.

Claims 1-4 are drawn to methods of preventing or inhibiting aging of an individual comprising cloning a body, an organ, a tissue or a cell of the individual and replacing the body, organ, tissue or cell of the individual with the cloned body, organ, tissue or cell. Claim 5 is drawn to a method of resurrecting an ancient creature using parthenogenesis. Claims 1-11 of '309 are to methods of maintaining the health of an organ and methods of treating a subject by replacing an organ with a cloned organ. The methods are obvious over one another because they both require that

organs be cloned and then used to replace organs in an individual or subject. The methods encompass parthenogenesis, and resurrection is the ultimate in organ replacement. Thus, at the time of filing the ordinary artisan would have found it obvious to arrive at present claims 1-5 given claims 1-11 of '309.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claims 1-4 are to methods of preventing or inhibiting the ageing of an individual. Claim 5 is to a method of resurrecting an ancient creature.

> "Credible Utility" - An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. (see Utility Guidelines, www.uspto.gov)

Claims 1-5 lack credible utility because at the time of filing a person of ordinary skill in the art would have believed that the ageing process could be either prevented or inhibited, or that an ancient creature could be brought back to life after death, which is the art accepted definition of "resurrection." Humans have searched for a mean through which to have eternal youth that is to prevent or inhibit ageing. However, to date such a prevention or inhibition has not been found. Further, bringing any creature back from the death is just not possible. Even with cloning, environmental factors would prevent the same creature from developing. The claimed invention lacks credible utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are drawn to methods of preventing or inhibiting aging of an individual comprising cloning a body, an organ, a tissue or a cell of the individual and replacing the body, organ, tissue or cell of the individual with the cloned body, organ, tissue or cell. Claim 5 is drawn to a method of resurrecting an ancient creature using parthenogenesis. The claims are not enabled because at the time of filing, the art did not teach methods of cloning across the myriad of species encompassed by the claims: at least mammals, fish, crustaceans, insects, amphibians and reptiles. However, the specification and the art do not teach methods of cloning except for a few mammals – bovines, sheep and goats.

The art taught at the time of filing that the particular methodology must be determined for each species, and that such methodology is not necessarily transferable from one species to another. In regard to this, Westhusin, states that one of the major factors influencing a successful cloning outcome is species of target animal. Westhusin goes on to state that while the basic methodology for nuclear transfer may be similar, the specific materials and methods do not automatically apply across all species. Westhusin outlines six factors which contribute to successful cloning: 1) acquisition of mature ova, 2) removing the chromosomes contained within the ova, 3) transfer of cell nuclei obtained from the animal to be cloned into enucleated ova, 4) activation of the newly formed embryo, 5) embryo culture in vitro, and 6) transfer of the cloned embryo into a surrogate mother. There is no guidance in the specification or the art on, for example, activation of enucleated Drosophila eggs or

lobster eggs, much less how to enucleate them for successful nuclear transfer. Westhusin further states that each of these steps will vary slightly between species, but that, more importantly, the efficiency of each step varies among species, ultimately affecting the ease of which a particular animal can be cloned (Westhusin, page 36-37, bridg. parag.). This analysis is supported by Polejaeva that states, in regard to the inefficiency of cloning, that several factors affect the inefficiency: laboratory to laboratory variation, oocyte source and quality, methods of embryo culture, donor cell type, possible loss of somatic imprinting in the nuclei of the reconstructed embryo, failure to reprogram the transplanted nucleus adequately, and failure of artificial methods of activation to emulate reproducibly those crucial membrane-mediated events that accompany fertilization (Polejaeva, page 1, parag. 2). Thus nuclear transfer, at the time of filing was not routine, but requires extensive experimentation without a predictable degree of success. Pennisi and several scientists working in the area of mammalian cloning point to a lack of general and reproducible success emphasize this. Robert Wall of the USDA is quoted as stating that despite years of effort, "[w]e're in the same bind that we've always been in. A majority of [would be clones] do not make it to term." (Pennisi, page 1722, col. 1, parag. 2, lines 9-14). Pennisi and Vogel state, "even when an embryo does successfully implant in the womb, pregnancies often end in miscarriages" (Pennisi, page 1722, col. 1, parag. 3, lines 16-18). Attempts to clone pigs using techniques successful in sheep were not successful; indicating that cross-species application of methodology is unpredictable (Pennisi, page 1725, col. 1-2, bridg. parag.). The case with rabbits indicates that obtaining an embryo by nuclear transfer does not translate into a cloned rabbit. While many cloned rabbit embryos can be made, they abort upon transfer to surrogate mothers, and in 2000, there had not been any successes in cloning rabbits (Pennisi, page 1725, col. 2, parag. 3). With primates, two cloned monkeys were produced, but there have been no subsequent successes in primate cloning (Pennisi, page 1726, col. 2, line 6 to col. 3, line 3). With regard to cats, one cloned cat has been produced, but given the difficulty in the art to produce a cloned cat and the lack of producibility as stated above, the cloning of cats is unpredictable. Two attempts to implant cat eggs or reconstructed embryos failed, providing

for an unpredictable outcome for cat cloning (Pennisi, page 1726, col. 2, parag. 3, lines 4-5). Others have reported establishing pregnancies but no report of a cloned cat being born (Pennisi, page 1726, col. 2, parag. 3, lines 5-9 and 11-12). As the authors state, establishing pregnancies is only part of the problem and is not a guarantee of a cloned mammal being produced (Pennisi, page 1726, col. 2, lines 9-11). Thus, at the time of filing, there appears to be such unpredictability that only the cloning of sheep, cows, and rodents were predictable. Particularly noteworthy, given that applicant's claims encompass the cloning of humans, is a report that the cloning of monkeys, a primate, by nuclear transfer had been successful when embryonic cells were the nuclear donor, not when somatic cells were used as nuclear donor (Mitalipov, abstract). Mitalipov further states, clearly, that somatic cell cloning, as is part of the present methods, has not been accomplished in primates (Mitalipov, page 1367, col. 2, parag, 3, lines 1-3). Simerly, states that in rhesus monkey NT units, DNA and microtubule imaging showed disarrayed mitotic spindles with misaligned chromosomes, which resulted in unequal chromosome segregation and aneuploid embryos (Simerly, page 297, col. 2, parag. 1, lines 5-11). Thus, primate cloning is unpredictable for all the reasons cited above. Thus, at the time of filing, the skilled artisan would need to engage in an undue amount of experimentation to implement the claimed invention without a predictable degree of success.

Further, the claims are not enabled as the claims state that a body, an organ, a tissue and a cell is cloned. However, the art, as indicated above at the time of filing, taught how to clone by nuclear transfer bovines, sheep and goats, there is no guidance on cloning a body, an organ, a tissue or a cell as an entity separate from the individual. Neither the specification nor the art teaches such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing as to how one would replace a body with a cloned body. If the original body was still alive, how does one replace that body? If the original body is dead, how does one replace a dead body? Further, there is no antecedent basis for "the body, organ ... in claim 1. Exactly what body, organ etc is being replaced.

Claim 2 is confusing because there is no antecedent basis. In claim 1, the method comprises cloning a body, an organ, a tissue or cell. Where are the undifferentiated cells produced? In what step does this occur?

Claims 3 and 4 are confusing because if you fertilize 2nXY or 2nXX clone bodies you will have a 3N nucleus, which will not likely develop. What steps are required for fertilizing a body? What is meant by "recovering telomeres?" Is that isolation of the telomeres? What is a clone body?

Claim 5 is confusing and vague, as parthenogenesis alone will not give you a resurrected ancient creature or any kind of creature.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wilmut et al (1997) Nature 385, pp. 810-813.

Wilmut teaches the production of sheep cloned from a 26-day fetus and the mammary gland of a 6-year-old ewe (page 811, col. 1, parag. 1, lines 1-3 and Table 1.) As the method of Wilmut cannot be distinguished from that of applicant, the prevention and inhibition of aging is an inherent property of the method. The method Wilmut uses parthenogenic activation (page 813, col. 1, parag. 2, lines 1-3). Further, both the sheep fetus and 6-year old ewe are resurrected as both were dead animals used as nuclear donors to produce cloned lambs. "Ancient" is a relative term not defined in the specific.

Both the fetus and ewe nuclear donors are "ancient" in that they lived prior to the cloned sheep. Thus, Wilmut clearly anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
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Art Unit 1632

June 16, 2004